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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,884	02/14/2001	Christopher J. Berry	57897-5005	3367

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	18

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/783,884	Applicant(s) BERRY ET AL.	
	Examin r Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-46,48 and 52-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 19, 2003 has been entered in Paper No. 16.

This Office Action is a response to Applicant's request for continued examination (RCE) filed May 19, 2003 in Paper No. 16, and amendment and response to the Final Office Action (mailed November 19, 2002), filed May 19, 2003 in Paper No. 17 wherein claims claim 47 is cancelled, and claims 34-46 and 48 have been amended. Currently, claims 34-46, 48, and 52-61 are pending in this application.

Claims 34-46, 48, and 52-61 are examined on the merits herein.

Applicant's amendment changing the limitation to an edible oil comprising a specific composition herein in claims 34, 36, and 44-46 filed on May 19, 2003 in Paper No. 17 with respect to the rejection of claims 34, 36, and 44-46 made under 35 U.S.C. 102(b) as being anticipated by Jandacek (3,865,939) for reasons of record stated in the Office Action dated November 19, 2002 have been considered and found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-46, 48, and 52-61 as amended now are rejected under 35 U.S.C. 103(a) as being unpatentable over Imai et al. (5,514,398, of record) and Jandacek (3,865,939, of record) and Lane et al. (5,591,772, of record).

Imai et al. discloses that a rice bran composition, γ-OZ, comprising sterols such as campesterol stigmasterol, sitosterol and their esters in about 19% wt, and cycloarterol in about 35% wt, and triterpene alcohol is useful as food additives in a food composition, food product such as an edible oil, and a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human. See abstract, col.1 line 10-17, 33 to col.2 line 22, col. 22-26, and claim 3.

Jandacek discloses that the edible oil composition therein comprising a plant sterol (a free sterol and a steryl ester) in 2.0-6.0% wt, which is known to inhibit or suppress cholesterol in the blood (see col.2 lines 28-68), is useful in a composition and a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human (see abstract, col.1-2, and Table 1 at col.3-4). Jandacek also discloses that this edible oil composition with effective amounts of active

ingredients is administered in the form of a food product such as cooking, salad oil or foodstuffs. See claims 1-6.

Lane et al. discloses that tocortrienols and tocortrienol-like compounds including a tocortrienol and a tocorpherol from plant source such as rice bran, are useful as food additives in a food composition (foodstuff) and a method of decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human and tocortrienols and tocortrienol-like compounds also have antioxidant activity. See abstract and claims 5-11 and 21-25. Lane et al. also discloses that the reduced levels of the total serum cholesterol and LDL and the raised levels of the HDL by tocortrienol compositions therein are within the instant claims (see Table 1-3 at col. 25-30).

The prior art does not expressly disclose the employment of a particular edible oil comprising the particular ratio of (i) a tocopherol, a tocopherol, or combinations, (ii) free sterols, steryl esters or combinations (iii) a cycloartenol; or a particular edible oil comprising the particular percentages of (1) about 10 to 30% of tocopherols, tocopherols or combinations, (2) about 2 to 20% of free sterols; (3) about 2 to 20% of sterol esters, (4) about 0.1 to 1.0% of cycloartenols, a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a particular edible oil comprising the particular ratio of (i) a tocopherol, a tocopherol, or combinations, (ii) free sterols, steryl esters or combinations (iii) a cycloartenol; or a particular edible oil comprising the particular percentages of (1) about 10 to 30% of tocopherols, tocopherols or combinations, (2)

about 2 to 20% of free sterols; (3) about 2 to 20% of sterol esters, (4) about 0.1 to 1.0% of cycloartenols, a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a particular edible oil comprising the particular ratio of (i) a tocopherol, a tocopherol, or combinations, (ii) free sterols, steryl esters or combinations (iii) a cycloartenol; or a particular edible oil comprising the particular percentages of (1) about 10 to 30% of tocopherols, tocopherols or combinations, (2) about 2 to 20% of free sterols; (3) about 2 to 20% of sterol esters, (4) about 0.1 to 1.0% of cycloartenols, a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human, since each component in the edible oil or a food composition and it's effective amount or the range of effective amounts, e.g., tocopherols, tocopherols, free sterols, sterol esters, and cycloartenols, are known in the art, e.g., the rice bran composition, γ-OZ, according to Imai et al. Moreover, the usefulness of these oil compositions or food compositions (foodstuff) is also known, i.e., useful in a method of decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human, according the cited prior art.

Therefore, one of ordinary skill in the art would have reasonably expected that combining these known ingredients in their known amounts to be useful for the same purpose, i.e., decreasing total serum cholesterol and serum LDL cholesterol and raising

serum HDL cholesterol in a human, in a composition to be administered would improve the therapeutic effects for treating hypercholesterol in human.

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of known effective amounts of known active agents to be administered according the disclosures of Jandacek and Imai et al. and Lane et al. is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Since all active composition components herein are known to useful to treat and prevent hypercholesterol in human, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's arguments filed on May 19, 2003 in Paper No. 17 with respect to the rejections made under 35 U.S.C. 102(b) and 103(a) have been considered but are moot in view of the new ground(s) of rejection above.

Additionally Applicant's arguments that (1) the prior art teaches away from the combination of the cited references; and (2) even if combined, the references do not teach the claimed invention, have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art.

As discussed above, the cited prior art, i.e., Imai et al. clearly teaches the combination and the known effective amounts of the components herein, e.g., the rice bran composition, γ-OZ.

As indicated in the previous Office Action (November 19, 2002), Applicant's results in Example 2-4 of the specification at pages 19-23 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive for the following reasons. The results herein are not seen to provide clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since the results from the testing on the employment of the oil herein do not show any additive effects on decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human. Moreover, there is no clear and convincing side-by-side comparison with the closest prior art. Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

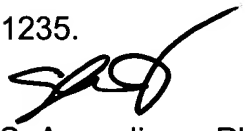
For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
July 30, 2003